mally required for each batch of cartridges to be characterised and for specific calibration values to be entered into the reader so that the assay response generated by the test cartridge can be normalised by the reader internally before the final assay result is reported. In the present invention, there exists the opportunity to utilise the buffer cartridge as a tool for transporting particular data of interest, for example assay calibration parameters about its associated batch of cartridges. One implementation could include the attachment of an EEPROM memory chip to the reservoir/reservoirs cartridge, whereby the data in the EEPROM memory chip can be read by the reader.

[0120] In one particular embodiment, the sample cartridge and associated reader are designed for carrying out an immunoassay, where the analyte to be detected is an antigen and the binding agent is an antibody. Paramagnetic particles may be functionalised by attachment of antibodies against either free or free and complexed antigen.

[0121] Due to the present cartridge design, importantly the only binding reaction that occurs initially is the antibody binding to any antigen in blood, this results in a number of advantages. Primarily it means multi-step assays can be performed, meaning the chosen label molecule/particle never contacts ("sees") the blood. This is a significant benefit over existing POC immunoassay technologies whereby both capture phase and label are in contact with the sample. The typical POC immunoassays binding schemes generally consist of either planar or magnetic capture particles and a label which could be bound to a particle, conjugate or polymer etc. However, both capture and label phase contact the sample (blood, plasma etc). This can lead to a number of problems. Within immunoassays there are many species that interfere with the immunoassay binding steps. Prime candidates are human anti-animal antibodies such as Human Anti-Mouse Antibodies (HAMA), animal anti-animal antibodies (in the case of veterinary applications), rheumatoid factor, anti-BSA antibodies, fibrinogen etc. Specific non-specific binding (HAMA, rheumatoid factor) and non-specific binding can result in highly inaccurate results resulting in poor performance and ultimately inaccurate diagnosis of patient samples. This is especially true as POC immunoassays are generally referenced to clinical analyser performance which incorporate multi-step assays, very effective wash steps and label detection in a clean matrix. Both specific non specific and non specific binding results in label bound to the capture phase in a manner not consistent with concentration of analyte (can be higher or lower than the expected result) resulting in an inaccurate result. Fluorescent latex particles may be employed which are functionalised by attachment of antibodies against free and complexed antigen. Thus a sandwich may be formed between the magnetic particles, antigen to be detected and fluorescent latex particles.

[0122] In one embodiment of the present system however, the detection label, such as a fluorescent moiety never contacts the blood, as the blood is washed away prior to any label being brought into contact with the bound analyte. Therefore any of these matrix events that could facilitate the non specific binding cannot occur because the magnetic beads (**18**) and detection label are not present in the blood at the same time, just like some clinical analyser systems. This is very important when considering the Allowable Total Error (ATE) of an immunoassay. There is a drive within regulatory authorities, such as the FDA to tighten the ATE on any new assay products to increase the accuracy of tests with respect to the reference systems.

[0123] For a given population of clinical samples, even if the majority of the bloods/samples recover accurately the ATE can be heavily affected by a few inaccurate responses. It is therefore very important that any new platform technology is designed to minimise these effects. The present invention aims to do that appropriate design of the cartridge and associated reader, thereby reducing sample to sample bias (e.g. elimination of specific non specific binding and non specific binding).

[0124] Another advantage of only performing the magnetic particle capture step in the untreated sample, such as blood is that blood measurements can become very accurate. Most immunoassays are highly sensitive with regards to reagent concentrations (i.e. concentration of the capture phase and label phase). Sufficient reagent concentration is required to drive slope whilst too high a reagent concentration results in increased assay intercepts. In a whole blood assay this problem can be further exaggerated as even if you deposit exactly the same reagent volume and concentration, the reagents will have different concentrations in different hematocrit bloods (as the reagents will resuspend in different volumes of plasma). For example, the same deposited reagents in a 60% hematocrit blood will have 1.87 times less volume than a 25% hematocrit blood. As a result the reagents will be more concentrated in the 60% hematocrit blood than in the 25% hematocrit blood. This alone could cause blood to blood bias problems as both the capture and label phase will vary in concentrations, therefore the overall capture efficiency (number of capture phase-analyte-label phase interactions made out of the total number of capture phase-analyte-label phase interactions possible=capture efficiency) will vary between bloods due to hematocrit effects alone. This further coupled with the varying viscosities of different bloods (and plasma's) affects the diffusion coefficients of any mobile reagent which can result in poor ATE.

[0125] Having only the magnetic particles binding analyte in the blood helps to significantly reduce this problem as the highly mobile and functional magnetic particles will be highly efficient with regards to binding the analyte. Therefore the magnetic particle concentration difference in high or low hematocrit bloods is less important as nearly all the available analyte is bound in this step. The blood to blood viscosities effects are further minimised by the applied cartridge heating, as there will be no temperature effect as the cartridge will always have a constant temperature as previously described.

[0126] For an immunoassay once unbound agents in the blood have been actively washed out of the sample channel out into the sink, the reader then delivers a small amount of buffer into the sample cartridge through a buffer inlet point on the strip containing either a dry deposition of antibody functionalised fluorescent latex bead (or other secondary binding reagents). The antibody labelled fluorescent latex bead is resuspended by the buffer and then pumped into the channel containing the magnetic particle-analyte complexes. The permanent magnet or electromagnet housed in the reader is still applying a magnetic field at this point and "holding" the magnetic particle-analyte complexes in place in the channel. Once the antibody functionalised fluorescent latex has been transported by the reader into the channel containing the magnetic particle—analyte complexes, the magnetic field is removed allowing a second binding reaction to occur.